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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,317	08/21/2006	**Christof Westenfelder**	10402-26	6531

7590 12/14/2009

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
12/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,317	WESTENFELDER, CHRISTOF	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 45-53* is/are pending in the application.

4a) Of the above claim(s) *2,4 and 11-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10 and 45-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/26/06, 6/5/07, 2/4/08, 3/30/09, 4/28/09, 6/26/09* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction/election requirement received on 9/28/09 has been entered. Applicant's election with traverse of the subject matter of Group I and the species "mesenchymal stem cells" as the species of cells to be examined. Applicant did not traverse the restriction between Groups I and II or Groups II and III. Applicant's traversed the restriction between Groups I and III, arguing that it would not constitute and undue burden on the examiner to examine the cell products of Group III with the methods of Group I. This argument is found persuasive in view of the elected species of mesenchymal stem cells, and therefore Groups I and III have been rejoined.

In the preliminary amendment of 9/29/05, claims 23-44, and 54-59 were canceled. Claims 1-22, and 45-53 are currently pending. Of these, claims 2, 4, and 11-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/28/09. Please note in regards to claims 11, 15-17, and 21 that the applicant has elected for examination methods of delivering mesenchymal stem cells to patient and not the delivery of differentiated cells such as endothelial or kidney cells, even if they were differentiated prior to delivery from mesenchymal stem cells, see also the election of species requirement mailed on 3/31/09, page 4. Claims 1, 3, 5-10, and 45-53 are therefore currently under examination based on the elected species of mesenchymal stem cells. An action on the merits follows.

Information Disclosure Statement

The information disclosure statements (IDS) filed on 6/26/06, 6/5/07, 2/4/08, 3/30/09, 4/28/09, and 6/26/09 have been considered with the following exceptions.

Portions of the information disclosure statement filed 6/26/06 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. No copies of the abstracts cited as A67-A89 were received with the 6/26/06 IDS. These references have been lined through as they have not been considered.

The IDS filed of 6/26/06 further lists for consideration the International Search Report for PCT/US04/09922. However, please note that the listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in

the Search Report have not been considered. It is further noted that although the non-Patent literature references listed in the Search Report were cited elsewhere in the IDS, no copies of Kim et al. and Imai et al. were provided.

Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-10, and 45-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Imai et al. (2002) Ped. Nephrol., Vol. 17, 790-794.

Imai et al. teaches therapeutic compositions of bone marrow, which Imai et al. teaches comprises both mesenchymal stem cells and hematopoietic stem cells (Imai et al., page 790). Imai et al. further teaches that transplantation of bone marrow into mammals results in the *in vivo* differentiation of the cells into renal cell types, including mesangial cells, renal tubular cells, and endothelial cells (Imai et al., pages 791-792). It is noted as well that Imai et al. teaches the transplantation of untransduced or genetically modified bone marrow cells to a host, where the

cells are autologous, such as the experiments in mice and rats, or allogeneic, e.g. transplantation in humans (Imai et al., page 791-792). Imai et al. also teaches that bone marrow transplantation can be used for accelerating the regeneration of injured tissues, for treating renal diseases, or in conjunction with renal transplant (Imai et al., pages 792-793). In regards to the limitation of claim 50 that the stem cells are delivered in a ration of about 0.1:1 to about 50:1 hematopoietic stem cells (HSC) to mesenchymal stem cells (MSC), it is noted that a ratio of about 50:1 HSC:MSC is inherent to compositions of bone marrow. Likewise as the ration of 50:1 HSC:MSC is taught in the specification to be a therapeutic ratio (see page 16 of the specification), the approximately 50:1 ratio present in bone marrow meets the claim limitations of claim 53. Thus, by teaching the exact methods steps and compositions as claimed, Imai et al. anticipates the instant invention as claimed.

Claims 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Fibbe et al. (2001) Ann. N.Y. Acad. Sci., Vol. 938, 9-17.

Fibbe et al. teaches a therapeutic mixture of mesenchymal stem cells (MSC) and hematopoietic stem cells (HSC) suitable for transplantation (Fibbe et al., page 15). Fibbe et al. further teaches a range of therapeutic ratios of HSC:MSC which encompasses a ratio of 1:1 HSC:MSC (Fibbe et al., page 15). Since the ration of 1:1 HSC:MSC is identified in the specification as a therapeutic ratio (see page 16 of the specification), the 1:1 ratio taught by Fibbe et al. meets the limitations of claim 53. Finally, it is noted that the intended use of a composition, such as the use of the claimed composition "for the treatment of multi-organ failure, organ dysfunction, or wound healing", is not afforded patentable weight in a product

claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). Therefore, by teaching a cell composition as claimed, Fibbe et al. anticipates the instant invention as claimed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your

application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633